REMARKS

Claims 3, 7, 9, 10, 58-63, 66, 82-85 and 95 have been canceled without prejudice. Claims 1, 4-6, 8, 11, 16, 19, 21, 28, 33, 37-38, 42, 47, 52, 64-65, 67-69, 86-94, 96 and 99-100 have been amended to better claim the invention. None of the amendments made herein constitutes the addition of new matter.

The Drawings

The drawings have been objected to as informal. Applicants have submitted herewith Formal Drawings together with a Transmittal of the Formal Drawings. It is believed that this submission satisfies the requirements in this application.

The Claim Objections

Claim 100 has been objected to as being of improper dependent form. Applicants have amended claim 100 to depend from claim 99. It is believed that this amendment renders the objection moot.

The Rejections under 35 U.S.C. 112 and 101

Claims 1, 3-4, 37, 42, 47, 52, 68, 83-89, 96 and 99 have been rejected under 37 U.S.C. 112, second paragraph, as allegedly indefinite.

Claim 1 is allegedly indefinite for recitation of "and/or". In the interest of advancing prosecution and without acquiescing to this aspect of the rejection, this phrase has been replaced with "or."

Claims 1, 42, 47 and 52 are allegedly indefinite for recitation of "at least" to modify "comprising". In the interest of advancing prosecution and without acquiescing to the rejection, this phrase has been omitted from these claims as amended.

Claims 3 and 68 are allegedly indefinite for recitation of "comprising" preceding a Markush group. In the interest of advancing prosecution and without acquiescing to the rejection, these claims as amended recite "consisting of".

Claims 4 and 37 are allegedly indefinite for being "unduly alternative". In the interest of advancing prosecution and without acquiescing to the rejection, claim 4 has been amended to reduce the alternatives recited. Applicants respectfully maintain that this claim as amended is not unduly alternative.

Claim 42 is allegedly indefinite for recitation of "Modified composition of any amino acid . . .." In the interest of advancing prosecution and without acquiescing to the rejection, this claim has been amended to delete recitation of "of any amino acid". Applicants respectfully maintain that this claim as amended is not indefinite.

Claims 83-85 provide for the use of a transformed plant, etc. but do not set forth any steps involved in the method. A claim is said to be indefinite where it merely recites a use without any active positive steps for the use as practiced. In the interest of advancing prosecution and without acquiescing to this rejection, Applicants have canceled these claims without prejudice.

Claims 86-87 are allegedly indefinite for inadequate antecedent basis for the recitation of "Storage organ". In the interest of advancing prosecution and without acquiescing to the rejection, claim 86 has been amended to specify that the storage organ is a tuber, and claim

87 has been amended to specify that the storage organ is a specialized stem. Applicants respectfully submit that these claims as amended are not indefinite.

Claim 88 is allegedly indefinite for recitation of "total content of the seed". In the interest of advancing prosecution and without acquiescing to the rejection, this phrase has been omitted from these claims as amended, and the claim specifies that the chimeric gene encodes sunflower SSA and the storage organ is a seed, and the claim is made dependent on claim 1. Applicants respectfully maintain that this claim as amended meets the requirements for definiteness.

Claims 88-89 are allegedly indefinite for recitation of "does not only increase the sulfurous content of the seed" because it is unclear whether other metabolites are also increased in the seed or whether the limitation indicates that the sulfurous protein content is also increased in other plant parts. In the interest of advancing prosecution and without acquiescing to the rejection, this phrase has been omitted from these claims as amended. Applicants respectfully maintain that this claim as amended meets the requirements for definiteness.

Claims 96 and 99 are allegedly indefinite for insufficient antecedent basis of "genetic construct". In the interest of advancing prosecution and without acquiescing to the rejection, this phrase has been replaced with "chimeric gene" in these claims. This recitation is supported by base claim 1.

<u>The Rejections under 35 U.S.C. 102</u>

Claims 1-16, 20-23, 28-31, 33-40, 42-44, 47-50, 52-65, 67-69, 83-85, 88-97 and 99-100 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by Molvig et al. (1997). Applicants respectfully traverse this rejection.

The Patent Office has alleged that Molvig *et al.* teaches the expression of the SSA gene in a plant under the control of the pea vicilin gene promoter for the purpose of modifying the content and/or composition of a metabolite in the storage organ, and, as a consequence, that the claimed method is inherently disclosed by the citation. Applicants understand that the Examiner considers that, by following the procedures described by Molvig et al., each of the metabolites encompassed by claim 3 of the instant application would be obtained irrespective of whether or not persons skilled in the art were attempting to modify those metabolites.

In the interest of advancing prosecution and without acquiescing to the rejection, claim 1 and the other independent claims have been amended herein to recite a process step that is not specifically taught by Molvig et al., specifically in the case of claim 1, the step of "determining the content or composition, or content and composition, of a metabolite in the storage organ". Claims 58-63 and 83-85 have been canceled without prejudice. Because there is no specific disclosure or teaching in Molvig et al. to carry out such a "determining" step, the rejection has been made moot and must be withdrawn.

Claims 1-11, 13-14, 20, 65, 67-69 and 83-85 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by WO 95/27068. Applicants respectfully traverse this rejection.

The Examiner has correctly acknowledged in paragraph 27 of the Office Action that WO 95/27068 does not directly teach modifying the content and/or composition of fatty acids, starch or fibre. To this, Applicants would add the other metabolites recited in amended claim 1, namely soluble non-starch polysaccharide, insoluble non-starch

polysaccharide and protein nitrogen, all of which were specifically recited in previous claim 3.

In the interest of advancing prosecution and without acquiescing to the rejection, reference to "endogenous anti-nutritional factors" is not recited in the amended claims.

Accordingly, the present invention as now claimed is not anticipated by the cited WO reference, and the rejection should be withdrawn.

The Rejections under 35 U.S.C. 103

Claims 1-65, 67-69 and 83-100 have been rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Molvig et al. (1997). Applicants respectfully traverse this rejection.

The claims are drawn to a method of modifying the content of mor or more metabolites in the storage organ of a plant by expressing a chimeric gene encoding a sulfur rich protein. The claims are also drawn to transformed plants, progeny or a plant part that comprises at least one copy of the chimeric gene in an expressible format and to the use of such a plant, et c to produce a food composition for consumption by animals.

The Examiner has correctly stated that Molvig et al. "do not directly teach modifying the content and/or composition of specific metabolites such as fatty acids, starch or fibre" and, as noted above, the content and/or composition of these metabolites are not determined in the Molvig et al. disclosure. Furthermore, the Molvig et al. disclosure would not have motivated one of ordinary skill in the art at the time the invention was made to modify and subsequently determine the content and/or composition of these specific metabolites.

In the interest of advancing prosecution and without acquiescing to the rejection, claim 1 has been amended to specifically recite that the content and/or composition of a metabolite in the storage organ of a plant is modified and determined, the metabolite being "selected from the group consisting of oil (fatty acid), starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fibre, and protein nitrogen". In this regard, we emphasize the distinction between the determination of total nitrogen in seeds as reported by Molvig et al. (which is not an accurate reflection of the seed protein content) and the determination of protein nitrogen which does accurately reflect the protein content.

It is well known in the art that the major nitrogenous compounds present in plants are inorganic N such as nitrate and ammonia; organic non-amino acid N such as nucleic acids; and organic N in the form of amino acids, which can be either free or incorporated into protein. The micro-kjeldahl assay, which involves chemical degradation of all forms of N to ammonia, is used to quantify total N, including all of the aforementioned forms. Non-protein N can account for a significant percentage of the total N in seeds, and this proportion varies between different species [Leask and Daynard (1973) *Can. J. Plant Sci.* 53, 515-522, Exhibit A; Petzke et al. (1997) *Plant Foods for Human Nutrition* 50:141-162, Exhibit B]. The proportion of non-protein N also varies with seed stage of development [Donovan (1979) *Aust. J. Plant Physiol.* 6:449-457, Exhibit C], during germination [Balasarawathi and Sadasivam (1998) *Plant Foods for Human Nutrition* 51:71-77, Exhibit D] or with different extraction methods [Bhatty et al. (1973) *Can. J. Plant Sci.* 53:651-757, Exhibit E; Periago et al. (1996) *Food Res. International* 29:489-494, Exhibit F]. Copies of Exhibits A-E are enclosed herewith. Thus, total N is frequently not an accurate reflection of the seed protein content. Protein nitrogen must be accurately measured using a technique that does not include other forms of nitrogen. Thus, the reporting by Molvig et al. of the levels of total N in transgenic and non-transgenic lupin seeds does not accurately reflect the relative levels of protein in the two types of seeds.

The Patent Office has alleged that it would have been obvious at the time the invention was made to substitute the pea, chickpea or rice plants of the present invention. However, in view of the distinction presented concerning the nitrogen content versus protein content, Applicants respectfully maintain that the Patent Office has erred in concluding that it would have been obvious to substitute the noted types of plants. Therefore, the rejection is not proper and must be withdrawn.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by a Submission of Formal Drawings, a Petition for Extension of Time (three months) and a check in the amount of $920 as required under 37 C.F.R. 1.17. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,

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MARKED CHANGES
09/508,979
Amendment of 12/7/01

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1. (Twice Amended) A ~~method~~ of modifying the content [and/or] or composition, or content and composition, of [one or more metabolites in the storage organs of a plant, said method at least comprising the step of expressing in the storage organ of said plant a chimeric gene that comprises a genetic sequence encoding a sulfur-rich protein placed operably in connection with a promoter capable of conferring expression on said gene in the storage organ of said plant,] a metabolite in the storage organ of a plant, said metabolite selected from the group consisting of oil (fatty acid), starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fibre, and protein nitrogen, said method comprising:

(i) expressing in the storage organ of the plant a chimeric gene comprising a nucleotide sequence encoding a sulphur-rich protein placed operably in connection with a promoter sequence capable of conferring expression in said storage organ; and

(ii) determining the content or composition, or content and composition, of a metabolite in the storage organ, said metabolite selected from the group consisting of oil (fatty acid), starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fibre and protein nitrogen, subject to the proviso that the modified metabolites do not consist of only the sulfurous protein content of a seed and/or wherein the content of an amino acid is modified, such modification is not the result of the presence of a naturally or artificially high level of that amino acid in the sulfur-rich protein.

4. (Twice Amended) The method according to [claim 3] claim 1wherein the metabolite is selected from the group consisting of total protein nitrogen content of seeds, [and/or the] fatty acid content of seeds, [and/or the] fatty acid composition of seeds, [and/or the] fibre content of seeds [and/or the] and fibre quality of seeds [and/or the content of endogenous anti-nutritional factors in seeds is modified].

5. (Once Amended) The method according to [claim 4] claim 1 wherein the total protein nitrogen content is increased.

6. (Once Amended) The method according to claim 1 [claim 4] wherein the [total] fibre content [is increased or decreased] or composition is modified.

8. (Once Amended) The method according to claim 1 [claim 4] wherein the fatty acid content is increased or decreased.

11. (Twice Amended) The method according to [any one of] claim 1 wherein the sulfur-rich protein comprises an amino acid sequence that is rich in methionine and/or cysteine.

16. (Twice Amended) The method according to claim 1 [claim 14] wherein the promoter sequence comprises the pea vicilin gene promoter sequence.

19. (Twice Amended) The method according to claim 1 [claim 17] wherein the promoter comprises a *Triticum aestivum* HMW glutenin promoter sequence [such as the Bx17 promoter sequence or the JAN808 promoter sequence].

21. (Once Amended) A method of increasing the protein nitrogen content of seeds of a plant, said method comprising:

(i) expressing in the seeds of the plant a chimeric gene comprising a nucleotide sequence encoding a sulphur-rich protein placed operably in connection with a promoter sequence capable of conferring expression in said seeds, said nucleotide sequence also positioned upstream of a transcription termination sequence; and

(ii) determining the level of protein nitrogen in the seeds, [at least comprising the step of expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant,] subject to the proviso that the sulfurous protein content of the seed alone is not increased.

28. (Once Amended) A method of modifying the fatty acid content of seeds of a plant, said method [at least] comprising [the step of] (i) expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant; and (ii) determining the level of a fatty acid in the seeds.

33. (Once Amended) A method of modifying the fatty acid composition of seeds of a plant, said method [at least] comprising [the step of] (i) expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant; and (ii) determining the level of a fatty acid in the seeds.

37. (Twice Amended) The method according to claim 33 wherein the fatty acid is selected from the group consisting of: [content of] myristic acid, [and/or] stearic acid, [and/or] gadoleic acid, [and/or] behenic acid, [and/or] lignoceric acid, [and/or] oleic acid, [and/or] linoleic acid, [and/or] linolenic acid [and/or] and erucic acid [is modified].

38. (Once Amended) A method of decreasing the starch content of seeds of a plant, said method [at least] comprising [the step of] (i) expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant; and (ii) determining the starch content of the seeds.

42. (Once Amended) A method of modifying the amino acid composition of seeds of a plant, said method [at least] comprising [the step] (i) of expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant; and (ii) determining the amino acid composition of the seeds, subject to the proviso that [the] said modified composition [of any amino acid] is not the result of the presence of a naturally or artificially high level of that amino acid in a sulfur-rich protein.

47. (Once Amended) A method of modifying the fibre content of seeds of a plant, said method [at least] comprising [the step of] (i) expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant; and (ii) determining the fibre content of the seeds.

52. (Once Amended) A method of modifying the fibre quality of seeds of a plant, said method [at least] (i) comprising the step of expressing in the seeds of said plant a chimeric gene that comprises a structural gene sequence encoding SSA placed upstream of a transcription termination sequence and operably in connection with a promoter sequence capable of conferring expression on said structural gene in the seeds of said plant; and (ii) determining the fibre quality of the seeds.

57. (Once Amended) The method according to claim 52 wherein the lignin content of the seed is increased.

64. (Twice Amended) The method according to any one of claims 21, 28, 33, 38, 42, 47 or 52 [or 58], further comprising the first steps of:

(i) introducing the chimeric gene into a plant cell, tissue, organ or whole organism; and
(ii) regenerating an intact plant therefrom.

65. (Twice Amended) A transformed plant produced by the method according to any one of claims 1, 21, 28, 33, 38, 42, 47, or 52 [or 58] or progeny of said plant, wherein said progeny comprises at least one copy of the chimeric gene in an expressible format.

67. (Twice Amended) A plant part derived from the plant according to claim 65 [or the progeny according to claim 64] wherein said plant part comprises at least one copy of the chimeric gene present in said plant or progeny in an expressible format.

68. (Twice Amended) The plant part according to claim 67 selected from the group consisting of: [comprising] leaves, stems, roots, shoots, seed, tubers and [or] flowers.

69. (Once Amended) The plant part according to claim 67 consisting of [comprising] seeds.

86. (Once Amended) The method according to [any one of claims 1, 21, 38, 42, 47, 52 or 58,] claim 1 wherein the storage organ is a tuber.

87. (Once Amended) The method according to [any one of claims 1, 21, 38, 42, 47, 52 or 58,] claim 1 wherein the storage organ is a specialised stem.

88. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and wherein the total protein nitrogen content of the seed is increased[, subject to the proviso that expression of the chimeric gene does not only increase the sulphurous protein content of the seed].

89. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and wherein the amino acid composition of the seed is modified [with the proviso that expression of the chimeric gene does not only increase the sulfur-containing amino acid content of the seed].

90. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and

wherein expression of the chimeric gene in the seed increases or decreases the fibre content of the seed.

91. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and wherein expression of the chimeric gene in the seed modifies the fibre [content] composition of the seed.

92. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and wherein expression of the chimeric gene in the seed decreases the total starch content of the seed.

93. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and wherein expression of the chimeric gene in the seed increases or decreases the total fatty acid content of the seed.

94. (Once Amended) The method of [claim 12,] claim 1 wherein the chimeric gene encodes sunflower seed albumin (SSA) and wherein the storage organ is a seed and wherein expression of the chimeric gene in the seed modifies the fatty acid composition of the seed.

96. (Once Amended) The method of [claim 12,] claim 1 wherein the [genetic construct] chimeric gene encodes sunflower seed albumin (SSA) and further comprises a promoter sequence which confers strong expression at least in the seeds of the plant.

99. (Once Amended) The method of [claim 12,] claim 96 wherein the [genetic construct] chimeric gene further comprises a transcription terminator sequence placed downstream of the [coding region of the structural gene] sequence encoding SSA.

100. (Once Amended) The method of [claim 100,] claim 99 wherein the transcription terminator sequence is the pea vicilin gene terminator sequence.